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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/167,088	10/06/1998	FRED D. FINKELMAN	91830/625	9944

26874 7590 11/14/2003

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EXAMINER
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GABEL, GAIENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/14/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/167,088

Applicant(s)

FINKELMAN ET AL.

Examiner

Gailene R. Gabel

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,4-23 and 25-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,4-23 and 25-33 is/are allowed.
- 6) ☒ Claim(s) 34-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/8/03 has been entered.

### ***Amendment Entry***

2. Applicant's amendment and response filed 8/8/03 in Paper No. 26 is acknowledged and has been entered. Claims 1, 20-23, 25-26, 29, 31, 33-34, and 37 have been amended. Currently, claims 1, 4-23 and 25-42 are pending and under examination.

### **Rejections Withdrawn**

### ***Claim Rejections - 35 USC § 112***

3. In light of Applicant's amendment and arguments, the rejection of claims 1, 4-23 and 25-42 under 35 U.S.C. 112, first paragraph, as containing new matter, is hereby, withdrawn.

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4. In light of Applicant's amendment and arguments, the rejection of claims 1, 4-23 and 25-42 under 35 U.S.C. 112, first paragraph, as lacking enablement for in vivo targeting, in vitro capturing, and measuring of any peptide, protein, or cytokine, is hereby, withdrawn.

**Rejections Maintained**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37, part b) is vague and indefinite in reciting, "second targeting moieties comprising paratopic molecules that immunoreact with the label of the first targeting moieties" because it is unclear how targeting moieties immunoreact with a label. Perhaps, Applicant intends that the second targeting moieties are labeled, i.e. labeled targeting moieties, that immunoreact with the first targeting moieties (as in for use in claim 20).

Claim 37, part c) lacks clear antecedent basis in reciting, "the targeting moiety".

**New Grounds of Rejection**

***Claim R ejections - 35 USC § 102***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 34-36 and 40-42 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tamarkin et al. (US Patent 5,587,294).

Tamarkin et al. disclose kits for measuring secreted cytokine comprising labeled antibodies, capture antibodies, buffers, standards, labels, and solid support (see columns 13-14). Tamarkin et al. disclose incubating a blood sample with a labeled targeting moiety, i.e. labeled antibody, that specifically binds cytokine, thus forming a cytokine - anti-cytokine antibody complex (cytokine bound to the labeled antibody), then reacting the complex to a capture moiety, i.e. polyclonal capture antibody, which recognizes many epitopes on the cytokine molecule to specifically bind the labeled cytokine - anti-cytokine antibody complex (see column 9, lines 48-53 and column 10, lines 19-43). The capture antibody is adsorbed to a solid phase support or carrier prior to reaction with the labeled complexes, i.e. biotinylated IL-1 (column 10, lines 18-43). The immunoassay system uses various labels for cytokine detection including enzyme labels, fluorescent labels, radioactive elements, or luminescent labels (see column 7, lines 13-20, column 11, line 13 to column 12, line 11).

7. Claims 37-39 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bunting (US Patent 4,271,140).

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Bunting discloses a first targeting moiety (ligand receptor or antibody) that specifically immunoreacts with a target analyte (polyepitopic ligand or antigen) and a capture moiety (second ligand receptor or antibody) which also binds the target analyte. Bunting further discloses a second targeting moiety (gamma globulin) that is labeled and that binds the first targeting moiety. See column 2. These compositions are embodied in a kit format (see column 10).

8. Claims 1, 4-23 and 25-33 are allowable.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

Gailene R. Gabel  
Patent Examiner  
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November 6, 2003

A handwritten signature in black ink, reading "Christopher L. Chin". The signature is written in a cursive style with a large, stylized "C" and "L".

CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800-1641